U.S. ENVIRONMENTAL PROTECTION AGENCY

PRESENTATION OF THE APPROACH

TO REEVALUATE ATRAZINE

U.S. EPA

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PRESENTATION OF THE APPROACH
TO REEVALUATE ATRAZINE
OPEN MEETING
November 3, 2009

MR. BAILEY: Good morning, everyone. My name is Joe Bailey, and I'll be serving as the Designated Federal Official for this FIFRA Scientific Advisory Panel meeting.

The topic for this meeting is presentation of the approach to reevaluate atrazine. I might add that this is an informational meeting to present the plan for reevaluation in 2010.

As the Designated Federal Official, I serve as a liaison between the Agency and the public and the panel to ensure that all FACA requirements are met.

Dr. Heeringa, sitting next to me, will be serving as the chair for this meeting, and the panel only provides independent, scientific peer review and advice...and advice to the Agency on pesticide issues. The panel only provides advice and recommendations, and EPA does all the regulatory and decision making and implementation authority associated with pesticide issues.

This meeting does provide an opportunity for public comment. I think it's projected to begin about 9:30 this morning. I have a number of people who have requested to make comments ahead of time, and if there's anyone else in the audience that wishes to make public comments, please let me or anybody else on the SAP staff here know, and if you do walk up and request to comment this morning, we'll have to limit your time to five minutes or...or fewer.

We have a public docket associated with the meeting as well. A number of comments have been submitted to that. It is accessible to the public, and...and the presentations and any other material that is brought forward during this meeting will be placed in that docket and available to the public within a few days as well.

After the meeting is over, we will prepare a meeting minutes or report, and that also will be available on the web site and...and in the public docket.

And I think at this point, I will turn the meeting to the chair, Dr. Heeringa.

DR. HEERINGA: Thank you very much, Joe. And as Joe mentioned, I'd like to welc...welcome all of you to this administrative meeting of the FIFRA Science

Advisory Panel with the subject and a briefing on the presentation of the approach to reevaluate atrazine.

Before we begin, I'd like to have the members of the permanent FIFRA Science Advisory Panel introduce themselves and begin with Dan Schlenk.

DR. SCHLENK: Good morning. My name is Dan Schlenk. I'm a professor of aquatic ecotoxicology at the University of California at Riverside in the Department of Environmental Sciences. My areas of expertise are primarily mechanisms of action, merging contaminants, and pesticides in aquatic organisms.

DR. HEERINGA: And I am Steve Heeringa, the chair, currently, of the FIFRA Science Advisory Panel. I'm a research scientist and professor at the University of Michigan. I'm an applied statistician by training.

DR. POPE: Good morning. I'm Cary Pope. I'm a professor of toxicology at Oklahoma State University Center for Veterinary Health Sciences. I'm a neurotoxicologist, and my primary interest is in toxicity of pesticides.

DR. PORTIER: Good morning. I'm Ken Portier, Director of Statistics at the American Cancer Society national home office in Atlanta. I'm an applied biostatistician with 30 years of experience in

agriculture and public health.

DR. CHAMBERS: I'm Jan Chambers. I'm a professor at the College of Veterinary Medicine at Mississippi State University. I'm a pesticide toxicologist with emphasis on neurotoxicology and metabolism.

DR. BUCHER: I'm John Bucher. I'm the associate director of the National Toxicology Program in Research Triangle Park at NIEHS. I have a general interest in all kinds of issues related to toxicology and...and carcinogenesis.

DR. HEERINGA: Thank you very much, members of the panel, and I think at this point, with those introductions, that we're ready to begin, and I'd like to turn first to Steve Bradbury who is deputy director of the Office of Pesticide Programs in the EPA. Good morning, Steve.

DR. BRADBURY: Thank you, Dr. Heeringa, and I'd like to welcome the panel to today's meeting and also thank Joe Bailey and the staff of the Office of Science Coordination and Policy for helping to organize the meeting today.

I'd also like to introduce some of the colleagues with me today before I just give a brief little background to today's meeting. Dr. Tina Levine

will be speaking after...after I finish my comments as the director of our Health...Health Effects Division.

Next to her is Don Brady who's the director of our Environmental Fate and Effects Division. Elaine Francis, Dr. Elaine Francis from Office of Research and Development is the national program director for ORD's pesticides and toxics research. And Dr. Ed Ohanian, to my left, is the director of the Health and Ecological Criteria Division in the Office of Water.

As we'll be discussing briefly this morning, the science review plan that will be undertaken during 2010 includes close collaboration with our colleagues in the Office of Research and Development and the Office of Water, so I wanted to make sure they were here with us today as...as we go forward and outline what we'll be doing over the course of the next year or so.

Tina...when...when Dr. Levine gives her comments, she'll introduce the members of our team or our team leaders who will be taking the point in...in going through the...the peer review process over the next year or so.

As Joe indicated, today's meeting is an informational meeting. It's a meeting where we're...we

want to share with you in words to complement what's in text with the paper that you all received about a month ago which is describing the...the science review plan over the course of the next year. So, the purpose of today's meeting isn't to get into the scientific issues associated with the upcoming peer review but to provide some context to the peer review and discuss, broadly, sort of the scope of each of the three peer reviews that we'll be having during the course of the coming...coming year.

What I'd like to do is just spend a few minutes providing a little context on...on atrazine and its regulatory history. We'll touch on some of the previous Science Advisory Panel reviews that we've had, and then I'll turn it...turn it over to Dr. Levine who can go into a little bit more detail on the context of...of the upcoming year.

Atrazine was first registered, actually, by USDA back in 1958 as a herbicide, a broad spectrum herbicide. It's used both at plant and post-plant, and, currently, it's primarily used in corn, sorghum production, sugarcane and, to some degree, in turf, especially in the southeast.

In the early '80s, in 1983, EPA issued a registration standard which was some of the early

phrases associated with the registration process and the re-registration process, and at that time, the Agency indicated that it wanted to keep track of the potential of cancer, carcinogenicity of atrazine, and also indicated the importance of groundwater and surface water protection with the use of atrazine.

Throughout the 1990s, there were a series of voluntary adjustments to the label or to the use practices of atrazine, and these primarily focused on risk reduction measures to ensure minimal exposure to surface water and groundwater, particularly in the context of drinking water sources.

And associated during the time frame of the 1990s, there were rate reductions, setbacks from wells, setbacks from stream banks and...and water bodies. Also at that time, the compound received a restricted use classification for just about all of its uses, and in large part, that was involving the need to try to keep the product from getting into the water due to runoff.

In 1994, the Agency initiated a special review for not only atrazine but the other triazine herbicides, and the focus of that special review was around the potential for atrazine to cause cancer as well as the importance of minimizing exposure of

atrazine to groundwater and surface water.

As we move from the '90s into the early 2000s, there were two SAPs that were held, one in 2000 and one in 2003. Essentially, the outcome of those Science Advisory Panel reviews was that atrazine was not likely to be carcinogenic in humans, and so, the concern about carcinogenicity was researched and studied during the '80s, during the '90s, leading to the SAP recommendations in 2000 and 2003 looking at prostate cancer, but sort of reaching the conclusion that it was not likely that atrazine was carcinogenic in humans.

In January of...of 2003, the Agency issued an IRED, an Interim Re-registration Eligibility Decision which culminated much of the science that had been developing over the last ten years. In that decision, we re-registered the product and incorporated some of the additional mitigations that I've described before in terms of protecting groundwater and surface water, also some additional protections for workers as well. And at that time, we also...the Agency also established a drinking water monitoring program to ensure the concentrations of atrazine in drinking water source waters as well as finished water did not reach our levels of concern.

In October of 2003, we issued a revised IRED or Interim Re-registration Eligibility Decision which included a memorandum of agreement with the registrants to sort of memorialize the monitoring programs for drinking water. It also established a monitoring program associated with ecological systems, in particular, assessing whether or not atrazine was reaching levels of concern in terms of protecting aquatic communities. Also, that IRED in October of 2003 summarized where we were in terms of looking at the potential effects of atrazine on amphibian gonadal development as well.

In 2006, the Agency issued a triazine cumulative risk assessment, and so, the atrazine Interim Re-registration Eligibility Decision became a Registration Eligibility Decision, because the cumulative assessment had been completed for the triazine herbicides.

Right now, atrazine is scheduled to initiate registration review in...in 2013.

Now, through all this time frame of the '80s and '90s into...into where we are today, as you all know, if not directly at least from your colleagues, your predecessors on the Science Advisory Panel, we spent a lot of time going through a number of

issues with the Science Advisory Panel to help guide us in...in interpreting the science and...and, ultimately, to inform our decisions, and let me just do a quick snapshot on some of those previous SAPs.

I mentioned the...the efforts to better understand the potential of atrazine to cause cancer and what some of its mechanisms and mode of action may be. There were peer reviews in 1998 as well as 2000 that led us to the conclusion, with your advice and counsel, that the neuroendocrine mechanisms of action likely associated with atrazine with the cancer observed in rodents is probably not...is likely not to be operable in humans. However, the neuroendocrine mode of action was an important mechanism for us to focus on in terms of our risk assessment in human health protection.

So, we went through that 2000 SAP, the conclusion that atrazine's mechanism of action was likely associated with the neuroendocrine mechanism of action. The cancer observed in rodents probably was not likely relevant in humans because of the differences in the biological models but focusing on that neuroendocrine mechanism of action as initiating events as being the focus of...of the risk assessment which was the focus, then, of that IRED in 2003.

In 2002, we also had a Science Advisory Panel looking at the cancer issue in, for example, prostate cancer, looking at a study in a manufacturing plant where atrazine was manufactured to determine whether or not there was an association between prostate cancer and atrazine exposure. The conclusion of that SAP in followup work was that it was not likely that atrazine was associated with the prostate cancer for the workers in that plant. However, the Agency continues to monitor the literature in terms of atrazine's potential cancer effects which I'll touch upon in a little bit.

In addition to the...the reviews regarding human health, we also through the 2000s met with you four times to discuss atrazine's potential role in terms of ecological effects and risk, and there were two Science Advisory Panels discussing...exploring the potential of atrazine to cause gonadal developmental effects in amphibians.

In 2003, we had an SAP that looked at literature that had been published at the time and proposed that the literature established a strong hypothesis that atrazine may be able to cause amphibian gonadal development effects, and we proposed a research or a study design to you to follow up on that

hypothesis, and we sort of worked through that.

And then, with your advice on that study protocol, asked the registrant, required the registrant to do that study protocol and then came back in 2007 with the results from that study as well as other literature that had been published in the open literature since that time and concluded from that peer review that at least up to 100 ppb atrazine, we weren't seeing effects on gonadal development. But again, focusing on ongoing research as it gets published in the literature since 2007.

We also spent some time, two SAPS, one in 2007 and one just this last spring, looking at the effects of atrazine on aquatic communities, in particular, getting feedback on how to interpret effects of atrazine on aquatic communities and how to integrate that with the monitoring program to help elucidate where there may be vulnerable watersheds in terms of...of atrazine exposure.

Given sort of where we are in the state of the science, our focus for 2010 is to focus on the human health effects as our...as our area of emphasis as we go into 2010, and we'll revisit some of the ecological effects after we get through the...the human health effect risk assessments.

So, what will be...if I could have the next slide forwarded please...what our white paper describes is a series of...of three peer reviews over...over 2010. We'll just wait a second and see if this slide will come up. There you go...so there will be a series of three Science Advisory Panel meetings, one in February 2010, one in April of 2010, and one in September of 2010.

As we put forth our science...our review plan, we wanted to take advantage of...of SAPs that we already had scheduled. As you know, in February 2010, we already had a Science Advisory Panel meeting scheduled on the issue of how to incorporate epidemiological studies with experimental studies and how to develop those lines of evidence and integrate those lines of evidence.

And what we've done is added a case study to that February SAP which will look at some recent epidemiological studies associated with atrazine and get some advice not only on those studies but also, more broadly, methodological insights into how to integrate different kinds of epidemiological study designs as well as, more broadly, how to integrate epidemiological studies with experimental studies.

So, in a sense a building block as we

move throughout...through the year. That panel meeting will also include some discussion around the agricultural health study and how to take a look at different ways of estimating exposure in different kinds of epidemiological studies and how to integrate some of that information.

In April 2010, we'll focus on experimental studies, both in vitro and in vivo studies, and review the previous risk assessment, review any new information that's come out since that time, and take a look at some of the critical aspects of hazard identification, dose response relationships, as Tina will describe in a bit more detail.

We'll also take a look at how our toxicological interpretation influences sampling designs in terms of monitoring drinking water sources to ensure the frequency of sampling matches the dosimetry that we're elucidating through the toxicological studies.

So, that's a new review that wasn't scheduled previously.

The September 2010 SAP, again, will build on an SAP that was already scheduled. As I mentioned before, we continue to look at the potential of atrazine to cause cancer. As I said, we've

determined that atrazine is not likely a human carcinogen.

However, we wanted to keep track of epidemiological studies as they progress and, particularly, the ag health study which has two or three studies that we anticipate being published this spring or summer which will be very important to take a look at the cancer issue.

So, in 2010, we'll not only take a look at the ag health study; we'll look at other epi studies in terms of cancer, non-cancer, integrate that with the animal or the experimental toxicology studies, and try to bring it all together in September, 2010.

In closing, before I turn it over to Tina, I just want to indicate that as we approach this peer review process, we'll be taking advantage of Agency guidance in terms of how we do risk assessments, in terms of the NAS.

And the risk assessment paradigm, using our risk characterization handbook in terms of ensuring transparency and clarity, consistency, reasonableness in how we interpret our assumptions and integrate the data and also be taking a look at the National Academy report on 21st century toxicology, the importance of toxicity pathways, and how to interpret the information

that will be before us.

So, with that, unless there are any clarifying questions, I'll turn it over to Dr. Levine now.

DR. HEERINGA: Thank you, Dr. Bradbury. Dr. Levine?

DR. LEVINE: Thank you. I would also like to thank the panel for all the time and effort you bring to bear on our risk assessments, and your input is critical to ensuring that our risk assessments are transparent and are based on strong science.

And I would like to introduce at least the shell of the team. There's going to be a lot of people in HED working on this over the next year. I would like to introduce the...the leads for the project. First, Dr. Anna Lowit who's to the left of Steve Bradbury is going to be the overall lead for the three SAPS, and she also has the lead on the February meeting.

And next to her is Dr. Elizabeth Mendez who is taking the lead for the April meeting that's going to look at the laboratory data.

And to the left of Ed Ohanian is soon-to-be Dr. Carol Christiansen who's finishing her Ph.D. in epidemiology and is going to take the lead on the

September meeting.

So, this is going to be...these are going to be our principal players, but there are going to be a lot of people going through a lot of studies and working through the issues.

And I...a lot of this I think Steve has touched upon and I will be brief, but as Steve said, we signed the...the atrazine RED in 2003, and we used the best available science at the time to support the RED, and we used well accepted and publicly vetted Agency guidance in the way we approached it and also had three SAPS on the human health side, the one in 1998 that looked at the mammary gland tumors in rats, the one in 2000 that looked at the neuroendocrine mode of action, and the 2003 SAP on epidemiology of prostate cancer.

We based our...our science on a mode of action approach as the foundation for our dose response and extrapolation from animals to humans and among humans, and the 2000 SAP supported this approach, and, basically, we believe that atrazine works via a neuroendocrine mode of action which ultimately leads to the various toxic effects that are seen in the animal data.

And as our point of departure, we used attenuation of the pre-ovulatory luteinizing hormone

surge as a biomarker of disruption of hypothalamic function, and that's what we are basing...based our risk assessments of various scenarios on.

In this year-long review, we'll be looking at a thorough, objective review of new science and integrating it into the existing science that we based our 2003 RED on.

We'll be placing emphasis on evaluating mode of action and action pathways to toxicity, because we believe that understanding how a chemical works in the body will help us better interpret dose response data, life stage susceptibility, and the factors that lead to susceptibility, and also that mode of action provides a strong science for explicitly considering human relevance, the relevance of animal data to...to human health effects.

We'll be reconsidering all aspects of the hazard assessment, specifically, the critical effects used to extrapolate risk, the points of departure used for the margin of exposure calculation and the relevant durations of exposure, and, finally, the...the life stage susceptibility and what impacts the statutory requirement for the 10x factor to protect infants and children unless we have strong science that, data that allows us to change that..

And as Steve mentioned, we're doing this through three SAPs, and so the rest of this talk is to basically try to provide a little bit more detail on the three SAPs.

Again, the February meeting has...has always been on the schedule, and it really has a broader purpose than just atrazine, but some of the atrazine data fits very well into the broad purpose of the February meeting.

We had planned to do this meeting for a while, because especially with all of the data coming out of the Ag Health Study which is a rather major prospective study of 90,000 certified pesticide applicators from North Carolina and Iowa, that's a collaboration between NCI and NIHS and EPA, both the pesticide program and the ORD scientists, we've been getting information and we're getting regular updates on various outcomes of the epidemiological prospective study, and we realized that we needed to develop a framework for incorporating this data...these data into our risk assessments.

So, what we plan to do in February is develop a white paper framework based upon...building on the human relevancy framework that the Agency already has, and...and that was a big part of what we

were planning to do in February, and we wanted to basically vet this framework with some case studies. And our framework is going to use, you know, weight of evidence approach and best available information for humans and animals, and will again, as I said, emphasize mode of action and toxicity pathways, and it's quite consistent with guidance that's already out there that maybe doesn't specifically address a little of the epidemiology data that may be coming down the pike.

And we also wanted to take advantage of...of increases of incident data. We've been beefing up our ability to analyze the data that we have from...from our 6A2 incident reporting and also from poison control center data, and so, we wanted to use this SAP to try and evaluate that, too.

So, we're going to have three case studies, and the first case study will be the atrazine-related case study, a review of several recent epidemiology studies that have been fairly well publicized and have come to our attention. And most of these, I think, are in the category of hypothesized...hypothesis generating, some, a lot of them are ecologic, and we will be soliciting comments from the panel on ways to consider these types of

studies in risk assessment.

And then, the second case study is going to involve the Ag Health, but it's not...it's going to be actually the exposure part of the Ag Health. We're going to be...we're in the early stages of performing a side by side comparison of the exposure assessment approaches used in the Ag Health study to those that OPP routinely uses. And the second component of the exposure assessment case study involved evaluating co-exposure to multiple pesticides.

The third case study will involve a retrospective analysis of reported human incidents from exposure to an organophosphate pesticide that historically has been used in residential settings.

It's important for the panel and the public to keep in mind that although the February SAP will explicitly involve consideration of some atrazine epidemiologic studies, there really is a broader intent for this meeting.

The second SAP in 2010 is planned for April and will focus on experimental laboratory studies, from both in vitro and in vivo situations, and we will discuss our preliminary considerations for the updated hazard identification and dose response characterization. And as I will discuss in a few

minutes, we will also be discussing...and, actually, Steve mentioned it... that we'll also discuss some of the drinking water monitoring issues.

We will be performing a comprehensive literature review of studies related to human health for atrazine. The April meeting will focus on our preliminary evaluation of these studies.

As I noticed...I noted a few minutes ago, we're going to emphasize mode of action as a starting point for thinking about the dose response and life stage susceptibility, and we will also consider those studies used in the 2003 assessment as well as more recent studies investigating a variety of hypotheses. For example, we have identified new studies on mammary gland development, neurotoxicity, endocrine disruption, immunotoxicity, and studies on atrazine metabolites that we will be considering.

In April, we will be soliciting comments on our preliminary review of the updated critical effects and our preliminary evaluation of dose response. And one of the key areas of interest in the new analysis will be evaluating life stage effects and considering the factors that lead to life stage susceptibility as we think about the science that informs the FQPA 10x factor.

As Steve told you a few minutes ago, the temporality of the critical effect is an important aspect of this risk assessment. This is because monitoring frequency for community water systems should be related to toxic effects being used to develop the human health risk assessment.

In light of this, we'll be putting a lot of focus during our analysis on considering developmental windows of susceptibility, time course of toxicokinetic and toxicodynamic factors.

Drinking water exposure is the major pathway by which people are exposed in the United States to atrazine. Temporal window is relevant for toxicity endpoints that inform the exposure assessment. Specifically, in a case where acute effects are of greatest concern, monitoring must be done more frequently to ensure that the peaks are detected and also if chronic effects, like cancer, are of greatest concern, then monitoring can be done less frequently.

For the September meeting, the Agency will solicit comments from the SAP on three areas, epidemia out...epidemiological studies on cancer and non-cancer effects, experimental studies/laboratory studies on cancer and non-cancer effects, and pulling it all together, the integrated weight of evidence,

hazard dose response and exposure assessment and characterization.

The epidemiology studies, we expect to have new studies from the Ag Health study. It's expected, I think, in the spring, and there will be other scientific reports, and there also will be the epidemiology studies that we first raise in February, in the February meeting next...that's coming up early next year, and other scientific reports.

We will discuss a weight of evidence approach in February which involves using the best available science from humans and animals, and we plan to apply this approach at the September meeting. Specifically, we will integrate all of the information in February and April along with additional epidemiology studies and do a new hazard characterization for atrazine.

In the event that new studies come out between April and September from in vitro or in vivo studies, we'll also include these. And at the September meeting, we'll provide our proposals for updated points of departure and FQPA safety factors.

We will also update our thoughts on sampling frequency considerations based on the April SAP and if there are any potential revisions in

sampling design options, or if any changes in the atrazine risk assessment are proposed, those will be discussed at the September meeting.

And in light of the new science and the feedback we get from the panel, the Agency will determine if the risk assessment for atrazine should be revised and whether the drinking water monitoring frequency requirements should be changed.

So, again, here is the summary slide that Steve gave you at the end of his talk. At the February meeting, we're incorporating the epidemiology study and human health incident data and risk assessment. We're also going to be doing some stuff on...work on exposure assessments in epidemiology and comparing them to other...other ways in which we assess exposure, and we're going to do a case study using recent atrazine hypothesis generating epidemiology studies.

In April will be the preliminary evaluation of in vitro and in vivo lab studies, preliminary identification of critical effects and dose response assessment and some discussion of the frequency of atrazine monitoring in drinking water sources.

And in September, we will focus on the

epidemiology studies for cancer and non-cancer, integrate everything into a weight of evidence and hazard characterization, and, again, revisit the frequency of atrazine monitoring in drinking water sources.

And with that, I thank the panel for their time and attention.

DR. HEERINGA: Thank you very much, Dr. Levine.

Just an opportunity for quick questions of clarification from the...the panel members for either Steve Bradbury or Tina Levine?

(No response.)

DR. HEERINGA: With that, I think we'll have an opportunity after the period of public comment, too. They will be here. Are we ready to move on then?

At this point in our meeting, then, I believe we're ready to move on to the period of public comment. I just want...

OFF THE RECORD

(WHEREUPON, there was a pause in the proceedings.)

DR. HEERINGA: Okay, let's return to the proceedings of our meetings. For anyone who has joined us through the teleconference line to...as a companion to the webcast, welcome to this morning's informational

meeting of the FIFRA Science Advisory Panel on the presentation of the approach to reevaluate atrazine.

We are at the point in the morning meeting where we have an opportunity for public comment, and we have eight parties that have registered with Joe Bailey to present public comment, but before we begin those, I would like to draw your attention also to the docket for this meeting in which there are...I won't try to count it but approximately eight double-spaced pages of registered docket comments from various parties who have submitted public comment, written form public comment and supporting materials for this meeting.

This morning, though, we're going to hear from eight public commenters representing various groups and various interests, and they will be called up to present in order that they were registered with Joe Bailey, and I'd like to begin with Scott Slaughter of the Center for Regulatory Effectiveness. So, Scott, are you here?

It could be possible to use any one of these microphones on the side.

MR. SLAUGHTER: That works. I'm Scott Slaughter, and I'm here commenting on behalf of the Center for Regulatory Effectiveness. We have three

comments at this point.

First, any alleged endocrine effects from atrazine should be reviewed and assessed by the endocrine disruptor screening program, not these SAPs, not any other process within EPA.

Second, these SAPs are not motivated by science. They are politically motivated.

Third, the EPA political appointees need to defend the SAPs and the EPA staff who've worked on atrazine in the past from the personal attacks on their competency that have been waged by various NGOs, blogs, and media and individuals.

The first point is that any alleged endocrine effects from atrazine should be reviewed and assessed in EDSP, not in EPA's proposed SAPs and not in some other context at EPA. EPA has already send out EDSP test orders for atrazine.

EPA told the EDSP SAP that the EDSP process would identify any endocrine effects by pesticides, including atrazine. If so, then additional review of endocrine effects by these SAPs or by any other parts of EPA would be an unnecessary and duplicative waste of resources.

If what EPA told the EDSP staff is not correct, then EPA should withdraw and rethink its EDSP

test orders for atrazine, because they do not do what EPA said they would do.

A second point is that EPA's new proposed SAPs have nothing to do with new science. They're all about politics. Atrazine had a clean review from EPA as of July, '09 on the EPA web site. Then, the NRDC published a propaganda piece about atrazine. A dying newspaper, the New York Times, then ran an unbalanced opinion piece based on the propaganda piece by NRDC. And, according to the Huffington Post, Senator Boxer then ordered EPA to go after atrazine, and EPA followed orders.

These SAPs are bad politics, and they're a colossal waste of scientific time. EPA hasn't even given this SAP any SAP charges. Consequently, we suggest that the SAP consider making its own charges and tell EPA not to propose any further atrazine SAPs until and unless the Agency can justify them on the basis of EPA-reviewed data that meet Agency quality standards, including the Information Quality Act predissemination review standards.

Our third and last point is that various blogs, NGOs, and individuals have attacked the competence and integrity of EPA career staff that have worked on atrazine in the past. Some of their attacks

have been directly at named EPA individuals and violate all civilized standards of professional debate.

Because EPA's assessment and regulation of atrazine has always been based on review by SAP scientists, these attacks also challenge the competence and integrity of the seven SAPs who have reviewed atrazine over the last 15 years under four administrations, including President Clinton's Democratic administration.

We ask the current EPA political appointees to publicly state their competent...their confidence in the competence and integrity of the EPA career staff and the SAP scientists who have reviewed and regulated atrazine in the past. This public statement of support is necessary to protect Agency staff and scientists who are being bullied and to demonstrate that science and civil discourse are still the rule at EPA.

Thank you.

DR. HEERINGA: Thank you very much, Mr. Slaughter.

At this point, we have a second public comment presentation which, in agreement and prearrangement with Joe Bailey, the Designated Federal Official, will run a little longer. This is a

presentation by Syngenta Crop Protection and includes Janice McFarland, Dr. Janice McFarland, Dr. Peter Hurdle, and Dr. Charles Breckenridge.

And if they would like to come forward, and why don't we use these chairs here on the side? I believe there is a presentation set of slides for the panel members that should be in your packet. Dr. McFarland will take the lead.

DR. MCFARLAND: Thank you, Mr. Chairman, for the opportunity to be here today and to the panel and also to EPA.

We look forward to...I'm Janice...I'm Dr. Janice McFarland, and my background is that I started with our company 23 years ago as a metabolism chemist doing guideline studies for...for...in the environmental animal and plant metabolism, guideline studies under EPA.

I then in 1994 was the manager of the atrazine, triazine special review at the initiation of that...at the initiation of that review and then stayed involved in the science regulatory process for the triazines since that time. I'm currently...and since 2000 have been the head of regulatory affairs for Syngenta for the U.S. and Canada and Mexico.

Syngenta, for a little background for

those who don't know the company, is a world leader in the discovery and development, registration and stewardship of agricultural tools. We currently steward approximately 75 different fungicides, herbicides, and insecticides. Atrazine we have been the principal steward of for the past 51 years and have greatly appreciated the thorough and comprehensive scientific reviews of that product.

I'm happy to be here today with two of our top leading scientists and all who have many, many years of experience on the atrazine safety profiles. They are Dr....to my far left, Dr. Charles Breckenridge. He's a senior research fellow with Syngenta, and he has been the leading mammalian toxicologist and the lead scientist on the mode of action of atrazine.

I also have Dr. Peter Hurdle with us. He is Syngenta's head of product safety for the U.S., Canada, and Mexico and has been the lead environmental exposure and monitoring and characterization scientist. We're all happy to be here today.

We'd like to thank the SAP for...I'd like to thank the SAPs for all the contributions on the work and review of atrazine over the last 20 years as well as the extensive work of the Agency scientists

who, throughout that process, there's been an advancement of not only basic research but the understanding of safety testing for both atrazine and for all products.

The thorough review that's been well documented in the white paper has been going on for some...for 20 years. It's an unprecedented state of the art science data base, and as Dr. Breckenridge will share with you, the regulatory endpoints are conservative and very protective.

Independent reviews, you often don't hear about the other regulatory authorities around the world have also confirmed atrazine's safety in recent years, and I'll go over that a little bit, but the process in the U.S. EPA has been very transparent, and since 2000 alone, there have been opportunities for more than 16 public comment periods. And as many of you know and have been involved with, there have been six SAPs alone since 2007 since the re-registration.

This time line we don't need to go into, because Dr. Bradbury and also Dr. Levine discussed various aspects of it. This is a time line just documenting all the different work since 2000, the key milestones and key regulatory milestones with the U.S. EPA, and if you go back, it was in the, as they

mentioned prior, it was '88 when the re-registration started.

An SAP was held in '88. In '88, also health advisory limits were established by the Office of Water, and the NCL was promulgated for the water standard for...was promulgated by EPA's Office of Water in 1991. The special review started in 1994.

There are some public comment periods that people don't realize have happened that...that really add to the transparency of the last 20 year review.

For instance, if you look at that '02 time frame and you see the public technical briefing on atrazine, prior to that, in '01 when EPA completed their preliminary health reviews and the preliminary science...environmental science reviews, those are put out for people to review and there are 60-day public comments. So, throughout this time line, there's extensive opportunity for transparent public comment and information exchange.

Around the world, there has been a systematic review. So not only by U.S. EPA, but a systematic comprehensive review by different regulatory authorities, and in this time...this particular graph is focused on the cancer decisions for the

International Agency on Research in Cancer. Looked at atrazine in 1999.

Different regulatory bodies to look at the registration, the registerability of atrazine and the cancer classification began with the European Union. The United Kingdom was the science rapporteur, and...and they looked at atrazine thoroughly in both '96, 2000, and then again in 2003.

The U.S. EPA, we all know here. Canada...Canada just completed their review of atrazine, and they came out with documents in 2003, '04, and then '07. And Australia came out with documents and reports and conclusions of reviews in '04 and '08.

If you look at the World Health Organization, the last column there, the World Health Organization and the United Nations Food and Ag organizations...that's a joint meeting for pesticide residues...was held in 2007.

For all of these different regulatory...regulatory authority reviews and decisions, they determined that it was non- genotoxic, atrazine was not genotoxic, that its mode of action was not relevant to humans, and gave the cancer classification as not likely to cause cancer in the

language of the different regulatory, that the different regulatory authorities use. Either not classifiable or not likely to cause cancer.

If you...when the reviews are extensive of many different studies. This is one just from the World Health Organization. It documents that the reviews are comprehensive, that the mode of action is well understood, that epidemiology research was reviewed and looked at, that atrazine is non-development...developmental toxicant or and...and it does not cause harm to fetuses, infants, and children.

Other quotes just from some of these reviews, often because atrazine is not registered in Europe, people erroneously conclude that that was due to science or health reviews, and that...that is not true. The science and health assessments conducted by European Union authorities, with the United Kingdom being their science rapporteur and France also held their own review, all determined that atrazine could be safely used. And so, the quote from France, they don't represent a public health. The United Kingdom, that atrazine can be used without harm to animal health or the environment.

And then, the most recent regulatory authority review around the world outsi...since the

cumulative risk assessment conducted by EPA in 2006 was done by the Australian regulatory authorities and determined that atrazine was not...not carcinogenic and also did not have developmental effects and could be safely used as a weed control tool.

With that as a backdrop, I'm going to turn over the...turn over the presentation to Dr. Breckenridge who is going to give a brief overview of the human safety assessment of...of atrazine.

DR. BRECKENRIDGE: Thank you, Janice. My name is Charles Breckenridge. I'm a senior research fellow with Syngenta. I have been involved with the atrazine safety profile and exposure characterization for more than 22 years now.

We at Syngenta were the first ones to discover that atrazine caused mammary tumors in 1986, and since that time, we have been working with a group of outside researchers to assist us to understand the processes associated with the cancer response in animals and, subsequently, other...other effects that we have proposed as the mode of action underlying that tumor response.

Some of my colleagues that are not here with me today and who have contributed substantially to the development of knowledge on atrazine include the

head of our endocrinology team, Dr. James Simpkins. He's from the University of North Texas, and you all have probably met him at earlier SAPs.

Dr. Robert Handa who's at...now at the University of Arizona, previously at Colorado State University, has continued to work on the mode of action relative to the effects on GnRH neurons. Dr. Russ Holvey from the University of California Davis is working with us today, currently on mammary gland development studies.

Evan Simpson is an aromatase expert from Prince Henry Institute in Australia, is working with us on stereogenic factor 1 and the postulate that atrazine regulates that factor and is responsible for aromatase expression. Jack Mandel, who's served with us on a number of epidemiology SAPs, particularly, the prostate cancer SAP, and has also done a critical case control study at our production facility relative to prostate cancer.

Jim Slinberg is an expert in weight of evidence characterization now at the University of North Carolina, Chapel Hill, has also been working with us over the years, and undoubtedly, you will hear from all of these gentlemen as we move forward with...with new data as it pertains to questions that are raised by

the EPA and the published literature.

For today, we intend to...to not take our standard approach of presenting data and reasoned logic and reaching conclusions. Rather, we intend to sort of summarize in a captioned way what has been known as we've gone through the development of knowledge on the atrazine hazard profile, exposure characterization and risk.

So, that is not the way we will operate in subsequent SAPs. We will present data. We will reason through logic, and we will reach scientific conclusions, and, hopefully, you'll concur with our interpretation of our own data and other data, but for today, we're just going to summarize in a nutshell what we believe to be true based on more than 22 years of research on atrazine.

And I should say, just as a...a first...they don't seem to be advancing...okay...so that we will give just a brief description of the comprehensive database that exists, the safety profiles that have been characterized, the safety standards that EPA has endeavored to set based on the effects that have been observed with atrazine in animal models, and the perspective of exposure relative to those safety standards, especially as it pertains to exposure via

drinking water.

This slide represents a...a picture of...of our database within the company, and each of these is not necessarily a single study, but it represents a project, and it comprises areas of study, including herbicidal properties, physicochemical properties, environmental fate transport, environmental effects, toxicity, mode of action, metabolism, kinetics, dynamics, risk assessment methodologies. So, that over the course of...of near 50 years, many studies have been conducted, and some of those have been brought forward and have shown to be greatly critical for this risk characterization for atrazine.

Other people have, obviously, developed an interest in atrazine as well. In the public domain, we keep track of published...any new published studies as, apparently, others do, and we note that there is an exponential growth in publications. We do pay attention to that literature, and to the extent that we see a study has implications that are critical for the human safety, we endeavor to investigate those studies and perhaps even try to replicate them and understand what they're telling us.

These are in vitro, in vivo, mode of action across the whole spectrum, and that's basically

our strategy of continuing to keep updated on what is happening in the literature relative to atrazine and whether or not the concepts that are developing in the literature that are at odds with the regulatory standards are our own perception of...of what atrazine does.

Now, in regard to regulatory standards, obviously, Syngenta and other registrants are obligated to provide specific high-quality studies that are well documented in terms of standards of excellence, and our database on atrazine has repeatedly grown and been updated as new concepts and new protocols have been developed and new approaches have been taken. In the areas of mutagenicity, we have within our own database and within the published literature, there are more than 50 studies.

When I speak of atrazine, I speak of atrazine in the mono and dealkylated metabolites as well as hydroxyatrazine, because effectively, EPA reached a conclusion which we concur with that atrazine should belong to a common mode of action group with the chlorotriazines, and so, when you speak of atrazine, you should speak of the chloro metabolites. We did lifetime studies on hydroxy metabolite as well which happens to be a...a major plant metabolite, and we

demonstrated that it, in fact, had a different mode of action distinct from the chlorotriazines.

So, in the course of studies that we've done, we've done full databases or part databases on the metabolites and as well as the parent. We've done mode of action studies in parent and we've done cross-over studies to metabolites so we can appreciate, in fact, where the toxicity might be coming from.

You should be aware that for a human that is exposed to atrazine, atrazine's half-life in the body is very short. It actually gets converted very quickly to the dealkylated metabolites and conjugated metabolites so that, in fact, the issue isn't atrazine. It's...it's the biotransformation products in the body, and we've been involved in that, in those investigations.

Overall mode of action work on the cancers led us to the first question, is it carcino...is it a mutagen, and the answer seems to be resoundingly clear that it is not, and that is pretty well, from our viewpoint, no matter how many additional studies might or might not get published, is off the table as a serious consideration for its mode of action.

We have studied whether atrazine

directly mimics estrogen, androgen, or the thyroid hormone. EPA's own research lab has been very much involved with this work. There are now more than 40 published studies on whether atrazine has estrogenic or anti-estrogenic properties, and in 2008, Aldridge, et.al. reviewed those studies and wrote up a...a weight of evidence on that. The conclusions are that atrazine does not operate as a direct hormone mimic in any of these vectors, and these are the principal targets for the endocrine disruption screening.

I think in 1994 when we first began this work, we kind of predated the concern for endocrine disruption. It turns out that atrazine had a mode of action relating to the endocrine system. We discovered that and today, I think, we're hearing a lot more interest in potential chemicals to do with effects on the endocrine system.

As has been stated, the cancer mode of action has been well characterized. We've been involved with that research over the years. So has critical labs in EPA's ORD. And from these studies have been developed the critical no effect levels that currently set the standard of exposure to atrazine, and this is based on the suppression of luteinizing hormone which was mentioned as a surrogate for the endocrine

effects of atrazine.

Just so briefly we can say what that...that comprises is that atrazine seems to modulate the GnRH neurons which are a small set of neurons located in the preoptic area in the hypothalamic region of the brain. They are pulse generators that lead to pulsatile release of GnRH which travels to the pituitary and causes LH and FSH actually to be released.

These have effects on the gonads, especially in females, to...to lead to ovulatory events and, in males, to regulate testosterone levels. And these processes play a critical role during onset of puberty in the sense that GnRH pulse generator plays a role in puberty onset as well as regulating reproductive function in the adult animal.

So, the LH suppression that we see with atrazine at high doses is actually a decent surrogate for its effects on the endocrine system. We've been working with Dr. Handa for a number of years to try to understand precisely how and where atrazine operates on the GnRH system, and you'll hear more about that research in...in subsequent meetings.

(W(WHEREUPON, there was a pause in the proceedings.)

DR. BRECKENRIDGE: So, the LH endpoints

that EPA utilized for short and long-term duration exposures in their 2006 chlortriazine cumulative risk assessment, I will focus on two of them. The first one is the...for covering 90-day exposures and exposures that extend throughout a lifetime. This is based on an LH effect, that is, LH LH suppression in the Sprague-Daly rat at 6 months of age or at 6 months of dosing, I should say, and this represents a no effect level, a 1.8 milligrams per kg with 1000-fold uncertainty factor, including a 10x FQPA factor leads to a reference dose of 0.0018 mg/kg, and that is the basis for what we believe would be an acceptable standard for setting the...the chronic exposure to atrazine in drinking water. We'll come to what the current standard is in a minute.

The second endpoint that was selected was 6.25 mg/kg no effect level from a study by Tammy Stoker in the ORD, a group in Research Triangle Park. She was studying a surrogate for LH suppression. She was looking at preputial separation in males, that is, the onset of sexual maturation in males which is dependent on testosterone and, in turn, dependent on LH release. She established a no effect level in this study, and this was about a 20 or 30-day study.

We have taken the liberty of plotting

the various studies available in the literature that we could find on the Sprague-Daly rat in terms of duration of dosing and effect on LH. So, these NOELs are actually LH no effect levels in animals at different durations of treatment. So that Ralph Cooper has done a study in 2000 where he dosed animals for either 1 day, 3 days, or 21 days.

The no effect level for effects on the LH system at 1 and 3 days was 300 mg/kg. We have recently, through collaborators in Dr. Handa's lab, published a study with Fidori that the no effect level for, I believe it was, a 4 or 5-day treatment was around about 100. Cooper at 21 days showed it was less than 100. Our own study, Morrisette in 1996...I think that was a 28-day study, Stoker's around about 21 days, at 6.25 mg/kg, and as I stated, the Stoker study actually sets the short-term reference dose for atrazine in regard to the LH effect.

And, finally, the long-term LH effect.

Now, you may think that this actually represents continuous effects of atrazine treatment on this LH system, but, in fact, it actually simply might reflect that the neuroendocrine system is very robust in the young adult animal, and as Sprague-Daly rats age endocrinologically, it becomes progressively damaged as

a result of continuous estrogen exposure.

It actually damages the arcuate nucleus and its regulatory process so that, in fact, this might simply reflect age-dependent deterioration of a control mechanism in the brain, and one would need a special set of studies to...to illustrate that point.

So, the aspect of the young being more sensitive in regard to this effect, it does not seem to be supported by existing data where the actual aged, endocrinologically aged animal has the lowest no effect levels, whereas the young animals tend to have less of a response.

Nevertheless, we come to finally taking those endpoints and establishing standards for drinking water, and the Agency has expressed concern about have we been able to properly characterize the frequency or the...the spikiness of atrazine exposure in drinking water. So, the postulate would be that somehow during a runoff event in agricultural season, we would miss a critical peak if we hadn't had very frequent monitoring.

But put that in the context of the actual no effect levels in single day NOELs and we derive DW LOC, you can see that, in fact, in the short term, the animal tolerates the...the dose much better.

So that single-day developmental NOEL, the Agency actually didn't use LH. They used a developmental NOEL from a rapporteur ecology study which is 13 days of treatment. That NOEL is 10 mg/kg.

The Stoker study for 30 days at 6.25, and the MCL was set in 1991 based on a chronic dog study where, in fact, that no effect level has been outdated to a...a higher level. That MCL, basically, has been in need of updating for...for more than 25 years.

Today, under the TCT cumulative risk assessment, EPA reached a viewpoint that 1.8 mg/kg is the no effect level of record for the most sensitive species in strength, and if you take that into a child, a child's body weight and water intake, you get a standard of 12.5 ppb considered to be safe in drinking water for lifetime exposure.

Those limits are brought forward to you today so that you can see them in the context of the subsequent presentation by Dr. Hurdle who will characterize the presence and amount of atrazine in drinking water over the course of many years of monitoring. So, with that, I'll turn the lectern over to Dr. Hurdle unless there's any questions. Dr. Hurdle?

DR. HEERINGA: I think we'll wait. Thank you, Dr. Breckenridge. Dr. Hurdle?

DR. HURDLE: My name is Peter Hurdle. I thank the panel for the opportunity to comment, and without much ado, I would like to jump into the next slide which is entitled comprehensive drinking water exposure assessment.

And very much like the presentation that Dr. Breckenridge gave about the number of studies that have been conducted, I have to say that drinking water exposure has been characterized by a huge number of research teams which include our own internal Syngenta research efforts, and we'll be speaking about that in a couple of minutes but also includes a huge body of data that has been generated under the Safe Drinking Water Act by the states, by universities, by academia, and by other research organizations.

So, what I will try to show you in the next couple of minutes is the comprehensiveness of the monitoring database, that impact exists and has been generated over the last 20-plus years. The...our ability to fully define the exposure protocols that...that consumers are potentially exposed to, we will actually show you that the current drinking water exposure levels demonstrate that we do achieve a large

margin of...of safety, and we will also show you that the stewardship measures that have been undertaken over the last 15 years since the mid '90s, the label change, the setbacks and other mitigation language effectively...have been quite effective in reducing environmental concentrations in both well and finished water.

So, if you...if you look at databases for drinking water exposure, data are generated, first and foremost, are the state drinking water monitoring programs which are community water systems that ensure quality control in their drinking water supplies to their consumers. You have about 51,000 community water systems in the...in the United States. About 40,000 of them are community systems and groundwater.

If you look at the actual analytical record that has been generated since '93, to date, there are about 212,000 samples analyzed in those programs. These are all finished drinking water, and the bottom line is that detects in groundwater systems are extremely infrequent. Less than 1 percent of the system has a detect of atrazine, and if you find it, it's very low. The resulting, resulting margins of exposure greatly exceed 20,000.

The margin of exposure would be here.

The actual maximum concentration people might be exposed to in a day or chronically as compared to the no effect level that was established for the appropriate time period.

Which leaves us about 11,000 systems on surface water that do provide drinking water to, in the United States. Again, all these 11,000 systems were candidates for drinking water monitoring under the Safe Drinking Water Act, and they do sample finished water. They typically take quarterly samples, so four samples per year, sometimes less, and most of the systems that are in areas of potential high atrazine exposure have a record of about 16 years of data, because they initiated the sampling program in 1993 and it's still active today.

So, this is the...the state database. The state database is supplemented by two high intensity sampling monitoring programs. The first one was voluntarily initiated by Syngenta in 1993 and continued until February, 2003. It included the most vulnerable community water systems that were producing surface water and supplying it as drinking water, mainly in water systems in the Midwest and in the South. We had up to 120 community water systems in that program.

It was a high sampling intensity program. It took between 40 and 60 samples per year in both raw and finished water which enabled us to fully characterize exposure protocols in the raw waters as well as in the finished water supply to consumers.

This program was replaced in spring of 2003 by the atrazine monitoring program which was a condition of the MOA Dr. Bradbury referred to earlier, and we have now a formal entry criteria for systems joining the monitoring program which was more conservative. Any system that had a single exceedance of 2.6 ppb total for triazines. AMP also looks for metabolites which is about the equivalent of 1.6 ppb atrazine joins the system.

And so, that program then included up to 151 community water systems in intensive monitoring. Took about 64 to 70 samples per year in both raw and finished water, mainly weekly and also some bi-weekly sampling during Q3 and Q4 and Q1. So, in a nutshell, if we look at surface water systems which are the ones with potential exposure to atrazine, we have a subset, a small percentage, of the high...most highly exposed systems in the U.S. under a high frequency, continuous monitoring program.

Systems will stay in the program for a

minimum of five years period.

So, what did we get from those programs? I summarize quickly the Safe Drinking Water Act monitoring program time record 1993 to '08. We have data for 47,000 community water systems. That's both ground and finished water. We have 212,000 samples in groundwater. We have 68 samples in finished surface water.

This data set is complemented by Syngenta's intensive monitoring data which included up to 151 vulnerable community water systems in a year. It looks into raw and finished. Both programs generated 64,000 finished surface water analyses in the most highly exposed systems.

Now, in a nutshell, if we look at the finished water samples, none of the more than 340,000 data we have on record from finished drinking water exceeded 100 ppb ever. By that, they didn't exceed the 209 ppb that Dr. Breckenridge mentioned earlier for short-term exposure as DW LOC. They did also not exceed the 298 ppb DW LOC that was published by EPA in their 2003 IRED.

If you look at it chronically, no community water systems in the AMP program which includes the most vulnerable systems with a very high

sampling frequency has exceeded 3 pb as an annual average in finished water since 2006.

So, we strongly believe that drinking water supply is safe.

Now, if we look at effectiveness of label changes and mitigation, what I'm giving you here is a view on the most vulnerable systems, surface water with high intense monitoring, so this is very precise data, and what we see here is the overall average of atrazine concentrations between 1994 and 2008. The years between '94 and 2002 are the voluntary monitoring program, and then we have the AMP which includes a few more systems.

So, what we see, that overall in those most vulnerable systems, finished water concentrations were at about 1.5 ppb in the mid '90s, and they consistently declined and have reached a level of about 0.5 ppb in finished drinking water by 2008.

If we look at well water in those same systems...we also took well water samples, high frequency...we see a very similar trend. We see a high level in the early '90s in well water which does not quite reach 3 ppb on average, and we see a consistent decline to levels just below 1 ppb.

So, both in raw and in surface water, as

a total average in those systems that are the most highly exposed in the U.S., we have had a 60 to 70 percent decline in concentrations in well water as well as in...as in finished water.

Peaks have been quite a bit of discussion and hype recently, and we do believe that we actually have a second program in place that gives us a good view on what peak concentrations could potentially be and how peaks could be characterized. This is the eco monitoring program that I'm referring to. Dr. Bradbury mentioned it as well as one of the conditions of the memorandum of agreement.

This is not drinking water. I am giving you here a little snapshot result. You might have seen this slide already. So, these are 45 watersheds in highly vulnerable settings, ecologically very vulnerable and with high atrazine use volume. We look in second and third order headwater streams, so these are not drinking water water bodies, but they might feed into some.

That program was initiated in 2004 and is still active today. We have over 10,000 samples analyzed. And the program was set up to focus on the run-off seas, and we run it for about four to five month right after the atrazine application season, so

we have a very good profile and characterization of potential exposure peaks.

This program has generated 190 site seasons of well resolved concentration time profiles for atrazine. Again, this is not drinking water, but the data, sampling data, we believe, can be used to serve as a worst case surrogate to describe peaks.

What do we see in those programs? Let me quickly talk about the eco monitoring program which is in the left upperhand box. We have about 10,000 data points. We have had a sampling schedule in 2004 and 2006, four days, grab samples. This was supplemented at about 25 percent of the sites with autosamples which were event driven.

And then, in 2007, we changed the program in order to be able to better describe peak concentration profiles to a daily sampling program. So, 2008, '07, 2008, 2009 generates data...daily samples, very tight time resolution.

This data set is, again, supplemented by a huge database that is available and has been generated over the last 40 years in surface water bodies. These are mainly studies that both were done under the USGS's monitoring program and other USGS programs. Heidelberg College has done a substantial

body of work.

Most of these programs were sampled on, the ones you see were sampled on characterizing runoff events. So, what did we see in those almost 120,000 environmental samples over the last 20 years?

We see that we have the peaks well characterized. We have a large body of data that is available for analysis, and we have never seen an exceedance of the 298 ppb drinking water level of concern in any of those environmental monitoring programs.

So, let me quickly talk about the concentration frames. You have seen this slide before. This is the overall average concentrations in the high...most highly exposed systems that grew in the voluntary monitoring program and the atrazine monitoring program.

If you analyze those data a little bit more thoroughly as statisticians would do and take only those community water systems that have a continuous record of at least nine years and reported both programs, you do get a highly significant statistical trend that shows you that concentrations in those systems have been declining between 1994 and 2006, and they have been declining more for systems

that were more highly exposed in 1994 than for a group that never exceeded an MCL of 3 ppb in 1994 and later.

Overall, the numbers are quite the same. We see a decline of about 60 percent to 70 percent in '06 relative to the baseline that we have in the mid '90s, and this was achieved without reducing the use volume of atrazine in those areas where these systems are located. So, the line at the top of the graph is the actual use volume of atrazine in those years.

Now, what that...what does that mean in terms of margins of exposure and...and human safety? What I, you know, give you here on this slide is an attempt to describe the worst case margin of exposure resulting from a single day exposure based on the data we have generated. So, you have the single day no effect level of 10 mg/kg/day which EPA used to define short-term exposure drinking water level of concern with a safety factor of 1000. You get...and the appropriate body weight and intake numbers. You get a concentration of 298 ppb.

What you have on the bottom right-hand of the graph is the probability of this situation of all samples that was generated in the AMP and BMP finished drinking water monitoring program. So, this is the full distribution of all the data, single day

values that were measured in those programs in finished water.

And if you do a margin of exposure calculation to be a single day no effect level, the resulting margin of exposure is in excess of 10,000 at the 99.9 percentile. If you do the same exercise for chronic and, just for simplicity's sake, I took the median here and compare it to the chronic no effect level of 1.8 mg/kg/day and the safety factor of 1000 which leads you if you want to reference those, if you look at the actual exposure resulting in the most...resulting from the most vulnerable systems, we're talking a margin of exposure as in excess of 200,000.

Please keep in mind these are the most vulnerable systems where you see exposure in drinking water.

So, in summary, we have a huge monitoring database. We have about 340,000 finished drinking water samples and 60,000 samples in ground water. We have 118,000 environmental water samples. We have broad geographic and temporal coverage in that data set. We have high sampling frequency in a significant number of data sets which is focused on monitoring locations. You have well characterized

peaks in runoff events based on daily sampling.

And if you take those data and put them into context of current no effect levels, all those data indicate that we have large margins of exposure which are in excess of 10,000. What we also see is that the label changes actually did have an effect. We had significant reduction in environmental concentrations. This is not only our own data. Also, USGS and state monitoring studies show that.

And with that, I hand it back to Dr. McFarland.

DR. HEERINGA: Thank you, Dr. Hurdle.

DR. MCFARLAND: The concerns about the process for this SAP are documented in our written comments that went into the docket, but as...but we know that it's an unusual situation for both the SAP to be in as well as us, because normally, we're providing basic research, data information that is actually addressing charge questions or specific reviews of scientific assessments, and in this case, we...we strongly feel that the new information that has been sparked by the attacks of the anti-atrazine group and also in the press do not justify opening a comprehensive re-review of atrazine.

But we are...we do remain confident and

will be really working hard, committed to fully and openly to contribute in the scientific process that lie ahead. We do ask that EPA be accountable for the scientific integrity of the pro...the regulatory review, and we appreciate and thank the SAP to help ensure that...that it goes through a scientifically rigorous process.

We have an unparalleled commitment to advancing the research in the safety assessments and stewardship of atrazine, and the past comprehensive reviews, we're appreciative of all of the efforts that went into those. It is an unprecedented data set on all levels of...of toxicology, risk assessment, exposure, and...and health assessments.

The regulatory endpoints, as you saw from both Dr. Breckenridge and Dr. Hurdle, are conservative and protective. They're...we are...we feel very fortunate and blessed, actually, to be part of such a transparent, open review process that has gone on for this product, and we also appreciate all the work from the past SAPs.

People, as I mentioned, often forget that the favorable registration decisions or safety assessments were...were not...not concluded only by EPA but by regulatory authorities around the world, and we

look forward to...to contributing science throughout the next part of this process, and are happy to entertain any questions from the panel now or if there are other questions after other public commenters.

DR. HEERINGA: Quick opportunity for panel members to ask questions of clarification of the Syngenta representatives. Dr. Bucher?

DR. BUCHER: John Bucher. Just out of curiosity, the specific technical part of water disinfection that would reduce atrazine levels, what...what can you tell me about that?

DR. HEERINGA: Dr. Hurdle?

DR. HURDLE: Well, as you probably could glean from the slides, there is an effect of water processing. As you process a lot of raw water to finished water, you see reduced levels in those finished water sources.

Therefore, I have...however, I have to point out so that there is an effect of water processing, water processing technologies do reduce atrazine levels. However, one of the remarkable points is if you look at the MCL which is the current standard that even the most exposed systems, on average, you do see that in all those sources, an average of far below that...that...that MCL to date which was wholly a

consequence of, you know, all the label changes that have been in the last 15 years.

DR. BUCHER: Thank you, but that wasn't exactly quite what I was asking. The aspect of the drinking water disinfection byproduct or the disinfection process that reduces atrazine levels, do you know what that, technically, what that might be?

DR. HEERINGA: Dr. Breckenridge?

DR. BRECKENRIDGE: I don't believe I could comment on the effect of disinfection byproducts modulating atrazine concentration. We know that the carbon filtration systems will modulate atrazine concentrations, if that's what you're getting at, but disinfection byproducts and their presence really don't...

DR. BUCHER: No, I'm sorry, I misspoke. I have that on my mind, because we deal with that all the time.

DR. HEERINGA: Dr. Hurdle?

DR. HURDLE: Well, I have just one add on to it. While we do know the hydrology stability under different pH conditions of atrazine, but...you know, and that's evident, so, there is data available that, you know, might instruct to that, but I'm not prepared to, you know, answer that question right away.

DR. HEERINGA: Dr. Portier.

DR. PORTIER: You talked a lot about community water systems. Has there been any measurement of...of well water, non-community water systems, residential wells in rural areas where there would be vulnerability?

DR. HURDLE: We have, in fact, done a pretty comprehensive rural well monitoring study in '92 to '94. We sampled about 1505 rural wells, if I'm correct, recall that correctly. We analyzed the well water for both atrazine and atrazine metabolites, and that data are available and have been related by EPA, so they're part of the atrazine database.

We did some resampling campaigns in 2000 and then again in 2007 to look at the most vulnerable wells and that could confirm exactly the same trend that you have seen here with the surface water systems. Levels have been declining significantly and consistently.

DR. HEERINGA: Okay, I'd like to move on, but I'd like to also thank Syngenta representatives for their presentation. Thank you.

Our next scheduled public commenter is Dr. Jennifer Sass who is representing the National Resources Defense Council. Jennifer, are you here?

Jennifer...Dr. Sass, are you here?

(No response.)

DR. HEERINGA: Not seeing Dr. Sass, we will move on to Dr. Joel Nelson who is representing California Citrus Mutual. Dr. Nelson? Take this chair where the mike's lit up there, if you want.

MR. NELSON: Well, thank you, ladies and gentlemen for this opportunity to participate in another SAP. For the record, I'm not a Ph.D., not a doctor. I'm not a lawyer, either, so I think I'm in pretty good shape.

My name is Joel Nelson. I'm president of California Citrus Mutual which is a citrus producers' trade association from California.

Now, you're probably wondering why I'm here, and last night or yesterday afternoon as I was flying into Washington, I was wondering the same thing. Been here, done that on several occasions, in my particular case, about four times relative to atrazine. But our industry is a user of simazine, a derivative of atrazine. And as goes atrazine, so goes simazine, and we know that.

So, a number of years ago...and our chairman will be testifying shortly...agriculture across the country formed an entity called the Triazine

Network, and we became part of the steering committee, and we began working with colleagues across the country on this particular issue, because we felt we had a responsibility, a responsibility to address the concerns, the legitimate concerns associated with herbicide use in agriculture.

For our industry, the citrus industry, we are weed free. We have to be. Our fruit stores on the tree. It constitutes a problem when weeds are pervasive in a grove. Creates a home for invasive pests, but just as importantly if not more so, we keep our groves warm without weeds by running water and wind machines. Weeds will make a grove colder by 3 to 4 degrees, according to scientific studies at the University of California.

So, it's in our best interests to keep our groves weed free. We don't till. Warmth is a serious, serious issue for us in the months of November 15th through, roughly, March 1st.

So, simazine has become an important product for our arsenal and our growers, 38...3500 producers, 285,000 acres, $1.8 billion worth of product. We're the number one citrus producing state in the nation. We got that way because of disease in Florida. They've lost their value. Ours continues to

increase, and we're proud of it.

But as I flew back here again, ladies and gentlemen, I wondered, why are we here again? And I was struck by the similarity of the occurrence in reading the documents from EPA. I was around when Fenton Communications started the Alar situation in public relations.

I was around when we had an adverse kneejerk effect with that public relations fiasco. It took a long time for the public relations industry to recover their credibility as a result of that, and there were a lot of chastened individuals as a result of that entire episode.

And I was around and went and saw Straw Dogs with Al...Al Pacino, and I remember what happened in that particular movie.

Well, ladies and gentlemen, as I read the documentation creating this effort, knowing that we have gone through this so many times and we're scheduled to go through it again under a normal process, why are we here again?

Well, we're here because government asked us to participate once again in a science advisory committee. So, all I say to you now is that the citrus industry from California, Citrus Mutual will

participate where appropriate.

I will admit I don't understand three-fourths of what you just...three-fourths of what you just heard. I'm a policy person. I can read conclusions. I have read your conclusions at EPA. Atrazine is safe. I have read your conclusions for 14 years. Atrazine, when used according to the label restrictions, is safe. I've read it relative to water. I've read it relative to carcinogens.

I've read it over and over and over again, and I'll wait for a conclusion, and I'll participate in a process, because that's what this is all about. It's another process. Let's be honest about it.

So, we have an obligation to participate, but on behalf of the citrus industry in California, you know we will be here. Again, when appropriate, call upon our industry, but please, don't ever address me as Doctor, because I can't wear that hat.

Thank you very much.

DR. HEERINGA: Thank you, Mr. Nelson. Somebody felt you earned it, but we'll track them down.

Our next public commenter is Gary Marshall who is here today representing Missouri Corn

Growers Association. Gary?

MR. MARSHALL: Thank you, Mr. Chairman. It is, I guess, good to be back here again. Seems like I was just here a couple of months ago, maybe three months ago, whenever it was, in June.

Again, my name is Gary Marshall, and I'm the CEO for the Missouri Corn Growers Association, and I also serve as chairman of a group that we have in Missouri called the Environmental Resources Coalition, ERC.

Environmental Resources Coalition is...is a group that we helped put together along with several government entities, including our Department of Natural Resources, the University of Missouri, a number of farmers in the State of Missouri, the farmers that I represent. And we used, over the years, some of EPA's 319 dollars to help address some of the areas of concern that we're talking about today, and talking about it again today, I must say.

You know, we have about 15,000 growers in the State of Missouri and over 300,000 farmers nationwide who utilize atrazine as a product. And...and I realize this is more about the science, but there's also the user community out there which I represent.

In Missouri, we use it on over...between 3 and 3.5 million acres, because the product works. It's better than anything else that we have access to today. Combining atrazine with other herbicides allows us to minimize weeds which compete for the nutrients and the water in our soils.

Beyond that, I have about 15 years' worth of experience in utilizing atrazine. In a previous life, we spread probably in excess of 200,000 acres over a 6 to 8-year period as a commercial applicator. So, I've utilized atrazine. I've utilized other products that are out there. I know what it does, and I know that it works.

And the farmers in Missouri tell us that it does work. It continues to work. In fact, in the last survey that we had, about $60...or $20 per acre, $60 million worth of savings by utilizing atrazine instead of switching to another product that doesn't work as well and that has a higher cost.

So, bottom line, it's right and appropriate for us to engage in this process. And we've submitted comments previous to this, and I'm not going to read those comments, but, you know, Halloween was just a few days ago, and it almost feels like Halloween again. Here we are again one more time.

It...it's scary, because I'd like to know when is enough enough.

You know, I've worked with scientists back in our state, and sometimes, 98 percent is good, and sometimes, 99 percent, and sometimes, I think here we're talking about 99.89, 99.92 percent. When is enough enough? We've got thousands of studies now, over 6000 studies, I think, reams of paper. I think the agreement is out there.

In fact, let me read just a quote to you that...that we found in EPA's own web site, and that is, the Agency has found that there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers from aggregate exposure from food, drinking water, and non-occupational sources to cumulative residues of atrazine and the other chlorinated triazine pesticides.

Now, that's what we go on. We trust the EPA. There's a process here that we've been involved with for a number of years. As...as Joel just mentioned, I'm going up, I think, on 14 years with the triazine network as a steering committee member, 13 or 14 years. I think it's been around for 15 years. And, again, I would say, when is enough enough?

We think that the science is there. We've seen it. We've looked at some of the new science that's out there. We don't believe that it tells us that we need to be looking again at more science.

So, I guess my comments would be that there's nothing new. This is kind of unprecedented. I think it's being driven by some folks out there that are anti-farming. They're anti-agriculture, and if that's true, you own it. If it is an activist agenda that is to ban all pesticides, well, we're going to be here. Just like Joel, we're going to be here. We're going to fight that.

We're going to use our connections wherever we have them to...to get our point across, because, again, we believe that the credibility of the EPA is at risk whenever we go back and we review, again, based on some...some new science that's out there that hasn't went through the same review process as the other science has that we've talked about over the last 12 to 14 years.

So, we look for the EPA to be non-biased, and...and we hope that the science, in the end, dictates the process. If the science dictates it, we're good to go. If it's politics, we're good to fight.

Thank you.

DR. HEERINGA: Thank you, Mr. Marshall. I believe that Dr. Sass has arrived, and given her earlier priority on the list, I call on her one more time. Jennifer Sass, Jennifer, are you here?

SPEAKER: She's here, maybe outside.

DR. HEERINGA: Okay. Maybe she just stepped...let's...I'm going to move on, then, to Mr. Jerry White who is representing the Kansas Corn Growers Association and Kansas Grain and Sorghum Producers Association.

Mr. White? I believe we have heard you before, too. Welcome back.

MR. WHITE: Yes, it's good to be back again.

DR. HEERINGA: Next up, Jennifer. Mr. White, please, and then we'll go to Dr. Sass. Yes.

MR. WHITE: Mr. Chairman and members of the committee, I guess it's good to be back again. My name is Jerry White. I'm the executive director for Kansas Corn and Grain Sorghum associations and serve as chairman of the triazine network.

The network did submit comments into the...into the docket, and so, I certainly won't go through all of...all of those, but to echo the comments

that were made earlier by Mr. Nelson and Mr. Marshall, we certainly are concerned that not only does it appear but I think in some of the not...been documented and reported that the SAP...it's not just the three that we're talking about in 2010 but also, according to a stakeholder conference call that several of us were on, there are additional SAPs, at least one additional SAP beyond September, 2010 that are scheduled in regards to atrazine.

And...and, certainly, we understand the process, that as new science comes out, new reports come out, that the Agency has a responsibility and obligation to review the new stuff that comes out and determine if it...or not it warrants a further review by their Science Advisory Panel, and we understand and appreciate that.

What we're not sure in this case is how we bypass some of that, what I call more formal internal review by Agency staff and, instead, have gone to a peer review by the New York Times. It seems hardly appropriate. The Agency itself, the assistant administrator, has indicated that...that the media reports are quite a bit of the driver for this.

Quite frankly, I'm confused about an SAP topic that's considered a kick-off meeting. It's

almost like it's a United Way campaign or, or something like that. It's...it's unusual, and at least from my standpoint, which probably doesn't go back as far as...as many of you, but this is SAP number six for me. So, it's not exactly a new experience.

You know, the agricultural community has participated for 15 years on this subject, will continue to participate. We do think the Agency and the SAP has done a...a tremendous job in the past. We've not always liked the positions taken.

The positions asserted by the Agency have not always been supported by the SAP, you know, I take you back to a previous administration and the issue of cancer. The...the presentations by the EPA at the time, widely reported again in the media the day before the SAP really began substantive discussions, suggested that, in fact, atrazine should be a carcinogen.

At the end of the process, it was not, but let's face it, the media had already had their field day, and they did not go back and readdress it in the same substance that they did report the initial presentations from EPA.

So, we've been there. We've seen the process work. We think we'll continue to see the

process work, and...and we'll be back, but we...we do point out that there are some very unusual things that seem to be going on.

We can appreciate that, but the sanctity of the science that's been a part of this review, it...it's...some of the most concerning things that I guess I've observed is a reference to things like the Bush EPA. And I'm just going to come straight out and say it.

In my mind, some of the most substantial science that occurred did not occur during the Bush EPA, if you want to call it that. The cancer issue was number one with a bullet when the special review was initiated, and, quite frankly, the body of science under that was done under the Clinton EPA, if we want to use those targets, and, in fact, the most substantial statement, I think, on public safety probably came out and on the review in total in July of this year by the Obama EPA.

So, it's a science that has carried the day through many administrations, and...and we certainly expect that to occur in the future, and I guess we'll look forward to seeing you again. I'm...I'm a little disappointed. I thought maybe I was going to be able to get a chance to hear his comments

some more, but I guess I should pass on that.

DR. HEERINGA: Thank you very much, Mr. White.

Just a note for myself as chair that this morning's meeting is a public meeting which is a public meeting of an annual update that the SAP, the permanent members you see here, receive from the EPA. And, generally, it is a...a general coverage of the topics that we expect to come down the pike in the next year and two years.

It is a little unusual that it's focused on one topic, but the fact that it's public, I think, in my view, reflects the EPA's interest in making this initial presentation which would, again, just be an administrative discussion with...with the permanent panel about upcoming things, to make that information open and available to the public.

At this point, Dr. Sass, we have your public comment.

DR. SASS: Thank you. I'm glad to be here, and I'm sorry that I was late. I will be here for the rest of the day. So, I will be looking forward to hearing your thoughts as well as the public commenters.

My name is Jennifer Sass, and I'm with

the Natural Resources Defense Council which is an environmental non-profit, and I'm based here in Washington, D.C., and I'm a senior scientist in the health program. My comments were submitted to the docket about a week ago or whenever they were. As well, I brought 30 copies in with Dr. Bailey to be distributed. So, hopefully, you know, you, at least, can access them at some point if you so desire.

So, I'm going to touch on some of the points in the comments. First of all, we're very pleased that the EPA and the scientific advisory panel will be taking a look at the atrazine issue for a number of reasons that are based on some new information that's come in, first of all, some of the monitoring, both water, ecological water monitoring as well as drinking or tap water monitoring information and some new science that's come out in the last few years.

As well, this science that was previously available to SAPs in earlier determinations is still very relevant, of course. There's no statute of limitations on the truth, and in this case, I think that the science has been increasing, making a stronger argument supporting the concern that atrazine in our waterways, both drinking water and particularly in the

wat...in open and surface water systems is a concern for wildlife.

So, first of all, at NRDC, we analyzed the drinking water and the ecological water monitoring data, and we have a report that's available, and I've also provided a summary in my comments.

Some of the main points are that the water monitoring from the watersheds, the surface water, showed that all 40 watersheds that were tested had detectable levels of atrazine, and this supports USGS water monitoring also that found widespread atrazine contamination in surface water. 25 of the watersheds that were looked at had average concentrations above 1 ppb which is the concentration at which primary production of aquatic, non-vascular plants such as algae is reduced. So, one would expect or predict that there might be harm to the ecosystem because of that.

Nine of the monitored watersheds, which is 22 percent of the total, had at least one sample showing atrazine levels above 50 ppb. This...this isn't an average, but it's a spike or one sample above 50 ppb, and four watersheds, representing 10 percent of the total, had peak maximum concentrations that exceeded 100 ppb.

So, this is a concern for us for aquatic wildlife as well as aquatic plants that provide oxygen and nutrients to the wildlife in the water.

One...at one place, the annual average concentration, that is, an average over the entire year, was 7.5 ppb. This is surface water at Little Pidgeon Creek in Indiana. And the maximum concentration in that location was 237.5 ppb. That was detected in May of '05.

We also looked at the drinking water monitoring data, and it also revealed some disturbingly high spikes or short-term peaks. More than 90 percent of the samples taken in the 139 water systems had measurable levels of atrazine over both sampling years. That was '03 and '04. And three water systems had running annual averages for atrazine in the finished or tap water that exceeded the 3 ppb drinking water standard.

54 of the water systems, representing 39 percent, had a one-time peak atrazine concentration that was above 3, and the highest peak in one of the systems was 36...39.69 in Evansville.

So, the...the peaks are a real concern to us because of potential effects on wildlife even during those short-term exposures which might be days

or weeks long. They don't actually...they aren't actually considered as peaks, per se, in the regulatory system for drinking water, and that doesn't fall under the Office of Pesticides' jurisdiction in any case.

And there's some new science as well that's worth taking a look at. In 2009, there was a number of studies published, and I want to just touch on some highlights from a...a meta analysis that was published by Drs. Rohrer and McCoy. Atrazine in that study...and that was a study on a wildlife species, frogs...found that atrazine reduced size at or near metamorphosis in 19 of the 19 studies that were looked at in the meta analysis. Responses were non-monotonic, meaning that sometimes metamorphosis was delayed, and sometimes it was accelerated.

Atrazine reduced anti-predator behavior in six out of seven studies that were looked at, and atrazine is associated with impaired immune function in 35 of 42 endpoints. There was an increased rate of infection in 13 of 16 endpoints. And atrazine altered gonadal development in eight out of ten studies that were examined. It impaired gonad function by altering spermatogenesis in two of the two studies that were looked at and altered sex hormone concentrations in six out of seven studies that were examined.

So...I'm not going to go through the strengths and weaknesses of meta analyses except to say that it raises some points that I think are worth taking a deeper look at in terms of the potential effects for atrazine on wildlife species, even in spikes or short-term durations.

There are some other significant studies that were published in 2009. One study, by Laws, et.al., found that even a single dose of atrazine...it was 200 mg/kg given to male oyster rats...caused a measurable increase in steroid hormone release within 15 minutes after dosing, so a rapid response to a short-term spike.

In another study, a different study, published in 2009, rats that were fed atrazine contaminated feed for one or two weeks had a dose-dependent reduction in sperm number and impaired daily sperm production. And in another study published in 2009, rats that were fed atrazine contaminated feed for 25 days had a dose-dependent reduction in steroid production in the leydig cells of the testes.

Finally, in another 2009 study, rats that were treated for five months with atrazine-laced drinking water at 330 or 300 ppb, which were within the range of the spikes or peaks that we're seeing in the

monitoring program, had associated insulin resistance leading to obesity. I think that one's very interesting, because it's so directly relevant because it was atrazine-laced drinking water was the dosing method, and the dose was just in the ranges of what we see in the monitoring program.

So, we are very pleased that EPA and the SAP is willing to take the time to look at this issue again. We have some recommendations for your scientific advisory panel as you put them together.

First of all, to gain assurances that EPA will provide all the published peer reviewed studies of relevant data, including but not limited to the animal bioassays, in vitro data, human epidemiology, incident data, and ecological epidemiology, that the questions and...the charge questions and the data provided to you should be broad so that your decision, your determination and your conclusions can be based on...on a broad sweep of the literature.

We recommend that SAP get assurances from EPA that it will...its review will not be limited to only studies published since the last review, given that previous SAP reviews did not do comprehensive literature reviews. They were...the charge questions

were more limited in those ones.

And we recommend that the SAP get assurances that the cancer and non-cancer review will include both human and animal data from published peer reviewed studies, including but not limited to the animal bioassays, in vitro studies, occupational epidemiology, and ecological epidemiology.

All data endpoints...all...sorry...all endpoints relevant to cancer, including endocrine endpoints, should be considered in order to help the SAP make a determination that considers the full sweep of the data.

Thank you very much for your time to do this.

DR. HEERINGA: Thank you very much, Dr. Sass.

We'd like to move on to our next public commenter. We have three more this morning, and then we'll take a break. It's a little different format. We've gone a little longer than we typically do, but we want to try to get through this period of public comment.

At this point, I'd like to ask Rob Schneider who is with the National Corn Growers Association. Mr. Schneider?

The remaining discussants in order, just so you can prepare, would be Alex Avery and then Wayne McAllister.

MR. SCHNEIDER: Good morning. It's good to be with you all today again. My name is Rob Schneider, director of public policy with the National Corn Growers Association, providing comment on behalf of NCGA which represents more than 36,000 members in 48 states, 47 affiliated state organizations, and more than 300,000 corn farmers who contribute to state checkoff programs across the country.

NCGA's members strongly support the continued use of atrazine as an agronomic necessity on about two-thirds of all U.S. corn. U.S. farmers rely on atrazine for cost-effective broad-leaf weed control.

First of all, NCGA is disappointed with EPA's decision to not extend the recent comment period on the atrazine reevaluation approach. According to the Agency, atrazine is one of the most widely used agricultural pesticides in the U.S., with approximately 7...70 million pounds of active ingredient applied domestically per year.

The chemical has been safely used in the U.S. since 1958, yet the Agency provided only 15 days for interested parties to submit written comments. If

EPA was interested in adhering to principles of transparency and sound science, it would have given adequate time for the public to review relevant materials and provide input.

In addition, the timing of this proposal in the midst of harvest made it particularly difficult for corn growers to meet the abbreviated deadline for comment submission. EPA's current course of action would suggest that it is prejudging the safety of atrazine, holding this meeting and determining the Agency's course of action within six business days of the close of the condensed comment period.

This week's meeting comes on the heels of almost continuous EPA review of atrazine over the past 10 years. The scientific advisory panels convened in 2000 and 2003, 2007, and 2009. There were additional studies already scheduled for 2010 before this current comprehensive review was announced last month.

During EPA's recent special review of atrazine, more than 6000 studies were considered in determining that atrazine's registration can be safely maintained. Perhaps what is most alarming is the precedent that is being established by the Agency's current action.

Before convening a scientific advisory panel, EPA would typically review any new applicable data or information, weigh its scientific integrity and regulatory significance, and determine the necessity of a new SAP.

This...there is no evidence that EPA has thoroughly evaluated any new underlying studies before proceeding with this particular panel. In fact, the Agency is attempting to review a host of issues in the next 12 months that previously took more than a decade to consider.

This creates a false sense of urgency and causes our members to question the motivation behind this process.

Our growers have always been committed to leaving our environment in better shape than we found it. Stewardship measures ensure that atrazine is used in accordance with the label and applied in a judicious and cost-efficient manner.

At the same time, NCGA believes that 50 years of safe use and extensive monitoring data support atrazine's continued registration in the U.S. In short, we are simply asking the EPA to stand by its own science.

NCGA and myself would like to thank you

for the opportunity to comment here this morning.

DR. HEERINGA: Thank you very much, Mr. Schneider.

For our next public comments, I would like to call up Alex Avery of the Hudson Institute where he is director of research.

MR. AVERY: Thank you for allowing us to...to be here and to comment. I've been in this arena for more than 15 years. I cut my teeth on the infamous Alar scare...scandal, really...that was perpetrated by the perpetrators of this current scandal. And I'm going to call a spade a spade today.

The announcement of this review a scant three months after the conclusions that were announced from the last decades-long review does not strongly suggest that this process is being entirely motivated by politics. It gives us a virtual high definition video of the politicization of the regulatory process.

It should be noted, as others have, that there was another review scheduled for next fall. There is not a shred of science that's been presented to suggest that a new, urgent, full evaluation is warranted or necessary, but the politics sure...sure do suggest urgency.

We all know if the Democrats lose the

next presidential election in 2012 that they will also lose the reins on the political machine with which to ban atrazine on political grounds. Hence, a new scientific review of atrazine must start immediately if the Agency and its, more importantly, its political directors are to have a fig leaf of science with which to hide their politically motivated ban or severe restrictions of atrazine.

And as the EPA is well aware, a ban or severe restriction on atrazine will mean higher food costs, more soil erosion, less sustainable farming, and more environmental degradation and damage. It will mean putting more of our farming eggs in fewer baskets, and with the inevitable return of bedbugs to our major cities, we've learned the hard way, just recently, how needlessly restricting the tools that we have to fight the scourges of Mother Nature hamstrings our efforts.

The world's population is continuing to grow, and world food demand is set to at least double over the next 40 years. We need every single tool we have and then some just to keep our heads above the rising tide of agricultural demand.

Atrazine is a critical tool in that process. It's also a critical tool in protecting the environment and keeping our agricultural system

sustainable. Atrazine and other herbicides are integral.

They're at the heart of the no plow, no tillage farming revolution that has caused soil erosion to drop precipitously, thankfully so. Research by the USDA at Beltsville has demonstrated conclusively that no tillage farming suffers less than 20 percent of the soil loss that organic and old-style conventional chillage, tillage plowing methods suffer.

And atrazine is a critical tool in that process. It helps us to combat resistance to other weed killers, maintain high...higher soil organic matter contents which is something that EPA is supposedly in favor of when it comes to climate change, and it protects our rivers and streams from sediment...sediment pollution which is also a major concern of the EPA under normal circumstances.

The witch hunt against atrazine has been perpetrated for more than a decade by the Natural Resources Defense Council, and they will not take no for an answer. And they realize that they don't need sound science or any good scientific evidence to justify a ban on atrazine. All they know...they know full well that, based on the Alar scandal, that all they need is innuendo. All they need is the suggestion

and enough concocted public fear.

And, hence, suggestions today from the...the one who came before me that atrazine is now responsible for the obesity epidemic in the United States.

So, back in the 21st century, the Natural Resources Defense Council was trying to do to atrazine what they did to Alar. Make no mistake, the NRDC and the political operators running the EPA today will go back to the scientific wishing well until they create enough innuendo and fear to cover a politically motivated, ideological effort to ban or severely restrict atrazine.

We are watching. We will fight it. We are not going away.

Thank you.

DR. HEERINGA: Thank you, Mr. Avery. And now, not Wayne McAllister but Ray McAllister from Croplife America.

MR. MCALLISTER: Thank you. I apologize for not having copies of my comments, but I'll make those available through the Agency.

Croplife America is a trade association which represents the common interests of manufacturers, formulators, and distributors of virtually all the

active ingredients used in crop protection products in the United States. We're commenting today because of our concern about the Agency initiating a...a review of a compound that has been reviewed almost continuously for more than 20 years, and the Agency has put a great deal of effort into this already.

In the course of making regulatory evaluations and decisions on individual products, the potential exists to set new policies and alter existing ones which will affect subsequent decisions across the board. That's our concern about the initiation of this review today which does not appear to be entirely motivated by science-based principles. We are not aware of any basis in...in real fact or law to reopen the long series of Agency decisions which are based on years of data on record and many years of the Agency analysis.

We're concerned that this...this decision for a new year-long review has been taken rather hastily and is based on un...unsubstantiated media...media reporting and reports of an activist organization over alleged human health effects and concerns and criticisms of EPA's regulatory oversight. The Agency announces as much in its public docket.

The Agency is well aware of the

importance of basing its rulings on sound science and a transparent progress, allowing adequate time for public participation. That is their statutory obligation, to adhere to these principles and frequently re..restate them in their communications regarding such actions and...and activities of the Agency.

Yet, this year-long review of atrazine involves a compound which has been in use for 50 years. It's been under a number of different types of reviews, many of them or some of them only recently concluded.

The Administrative Procedures Act requires notice and comment on actions by Federal agencies for a number of reasons. Public participation and fairness to affected parties is a principal reason. It ensures that the agency will have before it the facts and information relevant to a particular administrative problem, and it allows an agency to reconsider and sometimes change its proposals based on the comments of affected persons.

It doesn't specify a minimum comment period, but even providing 30 days to comment for the...from the publication of a Notice in the Federal Register might not be an adequate period of time to respond to proposals that are complex or based on significant scientific and technical data.

In this case, the compressed time schedule between publication of the notice of the meeting on October 7th and the call for public comments, a little more than two weeks later, for a meeting even just two weeks after that precluded considered and thoughtful comments on the review of the proposal by the public.

This compressed schedule also affected...gives the impression that EPA has prejudged the critical aspects of the year-long review of this compound and leaves no time for reasoned comment development by commenters, much less review of such comments by the EPA and adequate time for you, the SAP, to...to review and make appropriate recommendations to the Agency.

Under these circumstances, are we, as regulated entities and the regulated community, to conclude that EPA is establishing a new paradigm to take groundless and unsub...unsubstantiated information from the press and from activist organizations to start a new review of a compound? NRDC cites studies that have been reviewed numerous times and discounted by the experienced EPA scientists due to defects, flaws, or lack of quality in those studies.

We're concerned that this is a...this is

a divergence from the science-based process under FIFRA FQPA. EPA has done special reviews of triazines that took place over 12 years, concluded just 3 years ago. It has planned a registration review of atrazine to begin in just a few years from now. So, dropping another comprehensive year-long review in the midst of these other reviews in progress or recently concluded or on the schedule appears to be politically motivated, and we're concerned that this sets a precedent for other...other products in the marketplace where a review may be unjustified.

Thank you.

DR. HEERINGA: Thank you, Mr. McAllister.

A note to the presenters here during the public comment period. If you have a written version of your comments, including the version that you used to read from, and have not provided it for the docket, I would encourage you to do that, to provide it to ...to Joe Bailey who is the Designated Federal Official for this meeting.

At this point in time, I'd like to draw the period of public comment to a close and call for a 15-minute break at which time our meeting will reconvene, and we will have an opportunity, as we would

typically in our permanent panel administrative meeting, to address some questions to the scientific and administrative staff of the EPA.

So, let's all rejoin here about...oh, let's say 11:25, and we'll continue until about the noon hour.

(WHEREUPON, a brief recess was taken.)

DR. HEERINGA: Okay, welcome back, everybody, to the second half of our...our morning session, our morning meeting in which the panel is hearing from the EPA and from public commenters on the topic of the presentation of the approach to reevaluate atrazine.

At this point in time, we have on the agenda a period of time for the...the panel to discuss the material that we've heard this morning and to maybe ask questions of Dr. Bradbury and Dr. Levine, Dr. Lowit, and others on the staff who will be working on this particular effort.

I would like, if we could, to bring out the slide number 1 from Dr. Bradbury's presentation which is the...the columns are the three monthly meetings, and the rows are sort of a summary of content in each of those three meetings if we could.

And while that's...while that's coming

up, I guess I'd like to open up to my fellow panel members the floor to ask questions based on, again, the presentations this morning on the nature of this initiative. Does anyone want to take a leap? Dr. Portier?

DR. PORTIER: So, thinking about these...these upcoming meetings and, in particular, looking at the February meeting, we had a...we had a meeting last year where we looked at the three epidemiology studies from California. I don't know if you remember that meeting. Was it last year or year...late year before last? It was last year, early last year.

The community health work...the bystander exposure in epidemiology, but I just remember that panel and remember having a lot of discussion. I think it's going to be of importance for the panel to kind of see the questions for that meeting a little bit early so we can really understand what you're trying to get at in those questions.

It's been my experience on the panel that every time epidemiology studies come up, there's a lot of discussion and a lot of confusion. We spend a lot of time trying to understand the value of those studies, and sometimes, they're underpowered or

undersized, and then we're trying to figure out what are we really getting out of these...out of the studies.

And then, I guess, the second thing is if...if what we're going to be looking at is the agricultural workers study design, if you're going to be asking the panel to look at that design, to anticipate what we might be getting from that, it would be nice to be able to see those design parameters.

We...we were talking at the break about things like at this point, they should know roughly what their...their data collection rates look like, missing data, what kind of things it characterized, what kind of...what...what they actually measured, so we can be looking at those parameters and anticipating...I don't know if February's linked to September. In September, I'm thinking we're looking at the results of those studies. Right? Of whatever's published out of that study over the spring and the summer.

But if we're looking at kind of the value of epidemiology, we're going to need to understand up front what that...what was...what went into that particular study.

DR. HEERINGA: Dr. Chambers?

DR. CHAMBERS: With respect to the February study, it sounds like incorporating epi studies and human health incident data into risk assessment is a very important generic topic, and I assume that was what was on the table for February, anyway. I guess my question would be, is the atrazine data set really relevant to those particular questions, or are we going to get bogged down on just the individual atrazine data set? Because the generic questions, I think, might be broader than just the individual studies and...

DR. LEVINE: Well, actually, in my remarks, I think I tried to stress that we don't want that session to get bogged down to...into just being about atrazine, but...but we always envisioned this...this, the February session to have some case study examples.

And...and, in actuality, we had thought that they would be more of the data out of the Ag Health study that we could use, but that wasn't happening which is part of the reason it seems to get postponed and postponed, and since there were a number of different designs, designs that are different from the Ag Health study that were...were...have been cited in the media about atrazine risk and there are

other...probably other studies, too, we thought they would make good case studies. And, in addition, we have some incident case studies, and we'd always planned to do it that way.

So, it's really going to be one of the illustrations, but it's going to be about the more generic issue.

DR. LOWIT: And, Dr. Chambers, the only thing I would add to that...Anna Lowit. The only thing I would add to that is...is that the atrazine studies that we'll talk about are not, although they're unique to atrazine, those questions are not unique to atrazine, and there's not a unique situation where studies are published in the open literature that, on a pesticide chemical.

There's...questions always arise of how to incorporate that into our risk characterization. So, we share a concern of having atrazine not overwhelm that meeting and to focus on the broader intent, but I think the answer to your question is simply yes, the questions that we'll ask about those studies fit very well in that meeting, I think.

DR. HEERINGA: Dr. Bucher?

DR. BUCHER: John Bucher. I think the same kinds of comments could be made about the

references that you made, Dr. Bradbury, to the toxicology in the 21st century with respect to the ToxCast program that...the generation of data from in vitro assays and how that's used in risk assessment, and I'm...I'm not...I don't know exactly...in my own mind, I'm not sure exactly how mature that, the appreciation of all that information is going to be with respect to also inserting the atrazine issues in that regard.

So, I...I guess I just had some of the same concerns with that, that were just expressed.

DR. BRADBURY: With regard to...if I could read a little bit more into your question with regard, especially, to the April SAP, what we want to ensure that, consistent with Agency guidance on using best available information and developing of lines of evidence and weight of evidence to try to characterize the risk as best we can, think about the uncertainty either qualitatively or quantitatively.

We want to ensure that we're taking advantage of any in vitro information in the course of the data quality review of that data to see to what extent it can help inform us as to the mechanisms of action, mode of action of atrazine and how is that information concurrent with other experimental

toxicology information we review in April to see can we put together a coherent picture, maybe update the picture or maybe it's a new picture, in terms of what do we know about the mechanisms of action, toxicity pathways associated with atrazine and/or its metabolites and how does that lead to adverse outcomes, which we feel is an important part of doing a risk assessment today.

And we'll continue to advance that...the ability to try to integrate that information, to use toxicity pathways, mode of action to help inform dose response relationships, to help inform what may be similar or dissimilar across species and understand aspects of...of exposure considerations in terms of characterizing the risk.

So, that...April will be atrazine, but I think it's fair to say we'll not only advance our...and...and update our understanding of atrazine, but we'll probably get some other insights that can be more broadly applicable to integrating diverse sets of information together, especially as these go from April to...to September where experimental studies are being integrated with epidemiology studies.

If I could just comment a little bit on the earlier question about February/September, the

epidemiology studies, to...to reinforce what Dr. Levine was saying, our goal all along in February was to have a risk assessment to look at approaches for including incident data, as appropriate, as well as epidemiology studies, as appropriate, based on data quality and designs, all those issues, into a robust risk characterization and integrating this information.

February, in a sense, is a building block step as we move forward. And so, atrazine provides us some opportunity to explore some epidemiology designs as well as get some insights on some specific studies. I'm not an epidemiologist. I mean, I don't wear that hat, but my colleagues are explaining to me that there's a spectrum of design types from ecologic studies to retrospective case studies to prospective studies, and what we want to look at in February, in particular, are ecologic designs and retrospective designs and get some sense as to how you interpret that kind of information along with other kinds of information.

As we move to September, we'll be looking at the Ag Health study which is a prospective study which is a different design. We'll ultimately get some advice from you on how do we integrate these different kinds of epidemiology studies, designs or

strengths and limitations in the context of the animal or experimental toxicology data that we'll also have available.

DR. HEERINGA: Steve Heeringa. I'd like to introduce just a few comments of my own and...and these are my own views here and don't necessarily reflect those of the complete panel.

In the over...over a decade that I've been involved in the process with the ad hoc panels as a person who sat and provided advice or serving on the permanent panel, this is a little out of the ordinary, but I...certainly, it's not my position right now to question your judgment or the motivation on this.

We are an advisory panel and here to serve you objectively to help interpret science, and I think I certainly have worked with you long enough and have enough confidence to know that when you come to us, it's for a purpose to seek out scientific review on new information.

That said, this is going to be a very busy year, and these are going to be very demanding reviews not only for the permanent panel but also for the ad hoc members. And you know that the ad hoc members play a key role in these reviews. And it's going to be essential in this process, as it goes

forward...it's...it has some pretty broad aims, and I think, scientifically, as I say, we're prepared to help you evaluate those aims, and that's what we're going to do.

But it does mean that data sources, materials, background materials should be ready early in this process for review. The amount of data alone...if I think about even the April meeting with the sort of reassessment and look at the experimental toxicology studies could easily overwhelm reviewers, and I want to make sure that, as we go through this process as a panel, to be fair to you and to be fair to us, that we, in fact, have time to prepare.

And looking ahead to September with the Agricultural Health study...I have some knowledge of this because of participations in the meeting, but I don't know anything about the design.

Maybe it's a simple trip to the...to the web to learn some of that information, but I would say...ask of you in terms of your working with the permanent panel and also with the ad hoc panels that are formed that as soon as you have data and documentation that you can provide to us, it would be important for us to receive this even in advance of receiving the charge questions.

Because while the charge questions will help focus our scientific response to your concerns and your issues, I think it's very important in this very data intensive set of reviews for us to be able to become directly familiar with most of these information sources.

And...and we can communicate on that, too, but I just want to emphasize that, again, what you've presented here in terms of a scientific review, and we anticipate your request of us as an advisory panel on that science as we move ahead, please help us be prepared to do this. And we'll keep a close eye, too, because we want to make sure that there is adequate time for these reviews and for consideration of all of the information.

Additional comments? Dr. Chambers?

DR. CHAMBERS: As just a followup to Steve's remarks, then, if...if the data really can't be compiled in a well organized and well analyzed manner in time for those particular meetings, you've put meetings off before when they haven't been prepared, and maybe you should put those off, because we really do absolutely, the same thing Steve said, we absolutely need enough time to look at the materials.

DR. HEERINGA: Any other comments or

information? Steve?

DR. BRADBURY: Seeing if any of my colleagues had any followup questions. I want to take the opportunity to maybe clarify a few things and a little bit of feedback and, you know, move on.

First of all, I want to thank you all for spending the time with us this morning on an informational session just to share with you where we are, where our vision is in terms of taking a look at the science around atrazine.

As we mentioned before many times, administrative sessions are not public sessions, but we felt it was very important for this particular topic, as we look forward to the 2010 season, that we have a transparent session, we have an open meeting so people could provide some of their initial thoughts and clearly as we move forward through these three peer reviews.

And I certainly appreciate the timing and the need to get information in the docket as we form the charge questions.

But I just want to reaffirm that the process we use for each of these three SAPs will be like the process we typically use where information is put in the docket, there's opportunity for the public

to provide nominations to our colleagues and the designated official, federal officials, to vet a robust panel as well as the opportunity for people to look at the materials going into the docket and provide their insights on the information as well as their views on...on the charge questions as they're formulated as well as to offer you other issues that they think, the public thinks, are important to...to focus on.

And so, I just want to reassure the public as well as the panel that we will be using that same process that we've always done in terms of transparency and openness to get information. And, clearly, we will have a number of people working very hard to provide information as soon as we can, and we'll be working with Laura Bailey and others to ensure we have a good process in doing that, in getting information to you ahead of time.

And clearly, we value the input that you're going to be providing over the coming 12 months or so as we take a look at these issues.

The last comment I wanted to make was just to make it really clear again that when we come to the Science Advisory Panel it's to get advice on important scientific issues, and, clearly, scientific issues are the foundation for any and all of our

regulatory decisions, and we don't make regulatory decisions without having a good understanding of the science.

And so, coming to you is an important step in evaluating this compound and ensuring that we have the most current and accurate insights as to how to interpret the risk characterization of atrazine. And it's clearly our process consistent with Administrator Jackson's process of very strong science, the rule of law and transparency in how we make decisions, and the Science Advisory Panel looking, the scientists in OBT and ORD and Office of Water is an important foundation to...to how we take a look at this chemical and...and just to reassure everyone that the first step is making sure we're current with the science, we understand the science well and have the...the advice and input from this panel to help guide us in thinking about the science and that's the step that we're at right now.

So, I just want to close by thanking you all for spending time with us this morning and...and into the future, and we're very conscious of the aggressive schedule and the need to provide information in a timely manner.

Thank you.

DR. HEERINGA: Well, the lights dimmed because there was no activity. There was thought process going on, but I...apparently, it dropped to a certain level and it cut the juice.

So, Dr. Bradbury, if I could, just one more question. With regard to the epidemiology studies, the non-cancer that we'll consider in February and the cancer that we'll consider in...in September, are you aware of current work? Have you seen draft manuscripts on studies on ag health that motivate those agenda items? Or is it just the anticipation of the data release itself, the final data cleaning at a certain stage opens this up for reanalysis and publication?

DR. BRADBURY: With regard to the...the cancer effects in epidemiology, I mentioned in my opening remarks some of the regulatory process that atrazine is, is in. And atrazine is still in special reviews. The special review for atrazine hasn't been closed.

And the special review for atrazine and its primary focus was the extent to which atrazine could be a carcinogen and the potential carcinogenicity of atrazine. So, throughout our...our regulatory game plan time line for atrazine which includes closing the

special review, before we can close the special review, we needed to take a final look at atrazine and its potential for carcinogenicity.

And consistent with the 2003 IRED, it indicated that the Ag Health study that was ongoing, getting started at the time, and the forecasting for when the last atrazine studies would be completed would be roughly in this time frame.

So, that 2010 SAP was always scheduled to deal with the Ag Health study and the cancer studies within the Ag Health study as that last critical step of the science to then determine if we can close the special review for atrazine which had this remaining step in it.

Our colleagues in ORD and R&D and our individuals here in OBT with Carol, are working closely with colleagues in the National Cancer Institute and NIEHS, and it's our understanding that those final, I think it's two or three studies should be getting completed in the spring time frame, hence that's why we had scheduled September.

With regard to the other epidemiology studies, right now, we're focusing on studies that have been published in the peer reviewed journals. To the extent the Ag Health studies are looking at non-cancer

issues and they're coming to bear at the time, we would...we would fold those in as well.

So, our primary focus for Ag Health study was largely cancer, the last science step to determine if we can close the special review for atrazine. The other studies is more consistent with our holistic look at...at atrazine, epidemiology studies have been published since 2003 on non-cancer. We want to take a look at those. See how the different designs should be considered.

Again, we will be focusing on information that's been published in the peer review literature. To the extent something hasn't been published in the peer review literature, by definition, it's very difficult for us to review that. To the extent, I suppose if an individual or a research group wanted to submit their studies to the docket before they submit it into a journal, we would certainly take a look at them.

DR. HEERINGA: Thank you very much. Any other questions?

(No response.)

DR. HEERINGA: Well, at this point, I guess I'd like to turn the morning's proceedings over to Joe Bailey to see if there's any final

administrative notes, and then we'll wrap up.

I'd just remind everybody that the FIFRA SAP will reconvene...it's a larger group this afternoon...to address the topic of nanosilver, and that meeting will be chaired by Gary Pope, my colleague this afternoon, so we hope to see many of you back here for that this afternoon.

Joe?

MR. BAILEY: Thank you, Dr. Heeringa.

One note. Security has come forward and said there is a Toyota Forerunner on lower level 2 with the interior lights on, so if it's yours...it has Maryland plates. If it's yours, you might want to check it, or you will have to stay here for the rest of the meeting. If you weren't planning to.

And in closing, I just want to thank everyone for attending and express my appreciation to EPA staff and to the public commenters for their presentations. And I want to thank the panel and Dr. Heeringa for being here.

Thanks.

DR. HEERINGA: Yes, thank you, everyone, and we appreciate all of the participation, to the EPA scientific staff for their initial presentations and for bringing us to an open and public, transparent

discussion and for all of the public commenters for their input, and we look forward to seeing everyone over the course of the next year on this topic.

(WHEREUPON, the Meeting was adjourned at 11:55 a.m.)

CAPTION

The foregoing matter was taken on the date, and at the time and place set out on the Title page hereof.

It was requested that the matter be taken by the reporter and that the same be reduced to typewritten form.

Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.

CERTIFICATE OF REPORTER

COMMONWEALTH OF VIRGINIA

AT LARGE:

I do hereby certify that the witness in the foregoing transcript was taken on the date, and at the time and place set out on the Title page hereof by me after first being duly sworn to testify the truth, the whole truth, and nothing but the truth; and that the said matter was recorded stenographically and mechanically by me and then reduced to typewritten form under my direction, and constitutes a true record of the transcript as taken, all to the best of my skill and ability.

I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I certify that I am not a relative or employee of either counsel, and that I am in no way interested financially, directly or indirectly, in this action.

MARK REIF, COURT REPORTER / NOTARY

SUBMITTED ON NOVEMBER 3, 2009

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